



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS-3422-N]

Announcement of the Re-Approval of the American Association for Laboratory Accreditation (A2LA) as an Accreditation Organization under the Clinical Laboratory Improvement Amendments of 1988

AGENCY: Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: This notice announces the application of the American Association for Laboratory Accreditation (A2LA) for approval as an accreditation organization for clinical laboratories under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) program. We have determined that the A2LA meets or exceeds the applicable CLIA requirements. In this notice, we announce the approval and grant the A2LA deeming authority for a period of 6 years.

DATES: The approval announced in this notice is effective from March 23, 2022, until March 22, 2028.

FOR FURTHER INFORMATION CONTACT: Cindy Flacks, 410-786-6520.

SUPPLEMENTARY INFORMATION:

I. Background and Legislative Authority

On October 31, 1988, the Congress enacted the Clinical Laboratory Improvement Amendments of 1988 (CLIA) (Pub. L. 100-578). CLIA amended section 353 of the Public Health Service Act. We issued a final rule implementing the accreditation provisions of CLIA on July 31, 1992 (57 FR 33992). Under those provisions, we may grant deeming authority to an accreditation organization if its requirements for laboratories accredited under its program are equal to or more stringent than the applicable CLIA program requirements in 42 CFR part 493

(Laboratory Requirements). Subpart E of part 493 (Accreditation by a Private, Nonprofit Accreditation Organization or Exemption Under an Approved State Laboratory Program) specifies the requirements an accreditation organization must meet to be approved by CMS as an accreditation organization under CLIA.

II. Notice of Approval of A2LA as an Accreditation Organization

In this notice, we approve the American Association for Laboratory Accreditation (A2LA) as an organization that may accredit laboratories for purposes of establishing their compliance with CLIA requirements in all specialties and subspecialties. We have examined the initial A2LA application and all subsequent submissions to determine its accreditation program's equivalency with the requirements for approval of an accreditation organization under subpart E of part 493. We have determined that the A2LA meets or exceeds the applicable CLIA requirements. We have also determined that the A2LA will ensure that its accredited laboratories will meet or exceed the applicable requirements in subparts H, I, J, K, M, Q, and the applicable sections of subpart R of part 493. Therefore, we grant the A2LA approval as an accreditation organization under subpart E of part 493, for the period stated in the **DATES** section of this notice for all specialties and subspecialties under CLIA. As a result of this determination, any laboratory that is accredited by the A2LA during the time period stated in the **DATES** section of this notice will be deemed to meet the CLIA requirements for the listed specialties and subspecialties, and therefore, will generally not be subject to routine inspections by a State survey agency to determine its compliance with CLIA requirements. The accredited laboratory, however, is subject to validation and complaint investigation surveys performed by CMS, or its agent(s).

III. Evaluation of the A2LA Request for Approval as an Accreditation Organization Under CLIA

The following describes the process used to determine that the A2LA accreditation program meets the necessary requirements to be approved by CMS and that, as such, we may

approve the A2LA as an accreditation program with deeming authority under the CLIA program. The A2LA formally applied to CMS for approval as an accreditation organization under CLIA for all specialties and subspecialties.

In reviewing these materials, we reached the following determinations for each applicable part of the CLIA regulations:

A. Subpart E--Accreditation by a Private, Nonprofit Accreditation Organization or Exemption Under an Approved State Laboratory Program

The A2LA submitted its mechanism for monitoring compliance with all requirements equivalent to condition-level requirements, a list of all its current laboratories and the expiration date of their accreditation, and a detailed comparison of the individual accreditation requirements with the comparable condition-level requirements. We have determined that the A2LA policies and procedures for oversight of laboratories performing all laboratory testing covered by CLIA are equivalent to those required by our CLIA regulations in the matters of inspection, monitoring proficiency testing (PT) performance, investigating complaints, and making PT information available. The A2LA submitted documentation regarding its requirements for monitoring and inspecting laboratories and describing its own standards regarding accreditation organization data management, inspection processes, procedures for removal or withdrawal of accreditation, notification requirements, and accreditation organization resources. We have determined that the requirements of the accreditation program submitted for approval are equal to or more stringent than the requirements of the CLIA regulations.

B. Subpart H--Participation in Proficiency Testing for Laboratories Performing Nonwaived Testing

We have determined that the A2LA's requirements are equal to or more stringent than the CLIA requirements at §§ 493.801 through 493.865. Consistent with the CLIA requirements, all of the A2LA's accredited laboratories are required to participate in an HHS-approved PT program for tests listed in subpart I. The CLIA requirement at § 493.801(b)(6) requires PT

activities for the primary methods for nonwaived testing, whereas the A2LA requires its accredited laboratories to conduct PT activities for both primary and secondary test systems for waived and non-waived testing.

C. Subpart J--Facility Administration for Nonwaived Testing

The A2LA's requirements are equal to or more stringent than the CLIA requirements at §§ 493.1100 through 493.1105.

D. Subpart K--Quality System for Nonwaived Testing

We have determined that the quality control requirements of the A2LA are equal to or more stringent than the CLIA requirements at §§ 493.1200 through 493.1299.

E. Subpart M--Personnel for Nonwaived Testing

We have determined that the A2LA's requirements are equal to or more stringent than the CLIA requirements at §§ 493.1403 through 493.1495 for laboratories that perform moderate and high complexity testing.

F. Subpart Q--Inspection

We have determined that the A2LA's inspection requirements are equal to or more stringent than the CLIA requirements at §§ 493.1771 through 493.1780. The A2LA will continue to conduct biennial onsite inspections. The A2LA requires annual review of all accredited laboratories. Laboratories are required to submit any updates on information about its organization, facilities, key personnel, and results of any proficiency testing. Laboratories may be required to undergo an onsite surveillance visit if they do not submit their annual review documentation to the A2LA by the established 30-day deadline, if significant changes to the facility or organization have occurred, or if proficiency testing results have been consistently poor. The CLIA regulations do not have these requirements.

G. Subpart R--Enforcement Procedures

We have determined that A2LA meets the requirements of subpart R to the extent that it applies to accreditation organizations. The A2LA policy sets forth the actions the organization

takes when laboratories it accredits do not comply with its requirements and standards for accreditation. When appropriate, the A2LA will deny, suspend, or revoke accreditation in a laboratory accredited by A2LA and report that action to us within 30 days. A2LA also provides an appeals process for laboratories that have had accreditation denied, suspended, or revoked.

We have determined that the A2LA's laboratory enforcement and appeal policies are equal to or more stringent than the requirements of part 493, subpart R, as they apply to accreditation organizations.

IV. Federal Validation Inspections and Continuing Oversight

The Federal validation inspections of laboratories accredited by the A2LA may be conducted on a representative sample basis or in response to substantial allegations of noncompliance (that is, complaint inspections). The outcome of those validation inspections, performed by CMS or our agents, or the State survey agencies, will be our principal means for verifying that the laboratories accredited by the A2LA remain in compliance with CLIA requirements. This Federal monitoring is an ongoing process.

V. Removal of Approval as an Accrediting Organization

Our regulations provide that we may rescind the approval of an accreditation organization, such as that of the A2LA, for cause, before the end of the effective date of approval. If we determine that the A2LA has failed to adopt, maintain, and enforce requirements that are equal to, or more stringent than, the CLIA requirements, or that systemic problems exist in its monitoring, inspection or enforcement processes, we may impose a probationary period, not to exceed 1 year, in which the A2LA would be allowed to address any identified issues. Should the A2LA be unable to address the identified issues within that timeframe, we may, in accordance with the applicable regulations, revoke the A2LA's deeming authority under CLIA.

Should circumstances result in our withdrawal of the A2LA's approval, we will publish a notice in the **Federal Register** explaining the basis for removing its approval.

VI. Collection of Information Requirements

This document does not impose information collection requirements, that is, reporting record keeping or third party disclosure requirements. Consequently, there is no need for review by the Office of Management and Budget (OMB) under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 35). The requirements associated with the accreditation process for clinical laboratories under the CLIA program, and the implementing regulations in 42 CFR part 493, subpart E, are currently approved under OMB control number 0938-0686.

VII. Executive Order 12866 Statement

In accordance with the provisions of Executive Order 12866, this notice was not reviewed by the Office of Management and Budget.

The Administrator of the Centers for Medicare & Medicaid Services (CMS), Chiquita Brooks-LaSure, having reviewed and approved this document, authorizes Lynette Wilson, who is the Federal Register Liaison, to electronically sign this document for purposes of publication in the **Federal Register**.

Dated: March 17, 2022.

Lynette Wilson,

Federal Register Liaison,

Centers for Medicare & Medicaid Services.